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Steven Horan

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07/25/2008

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EXAMINER

MCEVOY, THOMAS M

ART UNIT

PAPER NUMBER

3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/779,315	<b>Applicant(s)</b> HORAN ET AL.	
	<b>Examiner</b> THOMAS MCEVOY	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50,52-61 and 63-88 is/are pending in the application.
- 4a) Of the above claim(s) 69-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-50,52-61 and 63-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This is the second Office Action on the Merits based on the 10/779315 application filed February 17<sup>th</sup>, 2004. Claims 1-68 are currently pending and have been considered below. Claims 69-88 are withdrawn.

### ***Election/Restrictions***

2. Upon further consideration, Examiner has determined that claim 40 is generic to both species.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-50, 52-61 and 63-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1 recites the limitation "an operator handle having a thumbscrew for movement of the catheter shaft relative to the inner core". Claim 40 recites the limitation "wherein the stabiliser component is adjusted by rotation of a threaded element which provides a position control device". Claim 61 recites the limitation "a pull handle having a thumbscrew for pulling the catheter shaft proximally relative to the inner core". The specification fails to describe exactly how the thumbscrew causes relative movement between the catheter shaft and inner core.

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Furthermore, although not claimed, the specification fails to describe how rotation of the thumbscrew causes relative linear translation between the catheter shaft and inner core. Therefore, Examiner has determined that any handle structure which causes the claimed relative movement can be considered as a thumbscrew, for the purpose of this examination.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "high compressive stiffness" renders the claim indefinite in that it is not clear what constitutes being "high compressive stiffness". It is unclear whether this is a compression feature or a bendability feature. Furthermore, "high compressive stiffness" is a relative term of degree which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See MPEP 2173.05(b).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8, 23-28, 30, 32, 39-41, 43-47, 50, 52, 53, 57-61 and 63-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker et al. (US 6,126,685).

Regarding claims 1 and 2, Lenker et al disclose a delivery system for delivery and deployment of a self expanding stent to a desired vascular location of a patient, the system comprising; a catheter shaft 72 (Figure 7) having a proximal end and a distal end, the distal end of the shaft defining a reception space (Figure 7, stent "P" is held within the lumen of 72) for receiving a self expanding stent, the stent having a reduced diameter delivery configuration (the stent fits into the distal end of a sheath 78 in a reduced diameter; column 7, lines 44-45); an inner core 34 engagable with the proximal end of the stent (as can be seen in Figure 2, the stent is disposed about, and therefore completely engaged by, the inner which further engages the stent at the proximal end with stay members 50; column 7 - lines 39 to 65); an operator handle (or thumbscrew) 40 for movement of the catheter shaft relative to the inner core to deploy the self expanding stent (Figure 6); a stabiliser component 60 (Figure 60); the inner core being fixed to the stabiliser component, at least during deployment of the self expanding stent (Figure 6; column 7, line 66 to column 8, line 13). Regarding claim 3, the inner core has a reduced diameter distal portion relative to the tip 256 (Figure 19) extending distally of the abutment at least partially through the stent in the reduced diameter delivery configuration of the stent. Regarding claim 4, the inner core 34 (at 42, Figure 2) forms a tubular member in the region of the abutment. Regarding claim 5, in light of the 112 rejection above, the device of Lenker et al. has a high compressive stiffness as compared to Jello perhaps. Regarding claim 6, the inner core is of a composite

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construction (column 8, lines 29-44) and has a high compressive stiffness relative to stent. Regarding claims 7 and 8, the catheter shaft comprises a distal sheath and a stent is frictionally coupled to the distal sheath in the delivery configuration (the stent, "prosthesis", is radially compressed by the sheath; Abstract). Regarding claim 23, the stent directly engages the distal sheath and is slidable relative to the sheath (the sheath radially compresses the stent; the stent is prevented from sliding out of the deployment area by anchors or stay members as described previously). Regarding claim 24, the distal sheath is a composite with a low friction inner surface (the frictional engagement of the distal sheath with the stent in order to release the stent, as described previously, shows that the inner surface has low friction under the broadest reasonable interpretation of the term). Regarding claim 25, the distal sheath is reinforced to withstand the radial stresses of the stent in its constrained reduced diameter configuration (column 8 - lines 29 to 38). Regarding claim 26, the inner core is fixed to a component of the delivery system (the inner core can be fixed to the stabilizer or journal sleeve; column 7, line 66 to column 8, line 3). Regarding claim 27, the component of the system to which the inner core is fixed comprises the handle. The inner core can be fixed to the stabiliser or journal sleeve (column 7, line 66 to column 8, line 3) which surrounds the proximal end of the catheter and therefore can be grasped, where the catheter of the reference does not require another sheath for insertion and operation. Movement of the stabiliser and inner core relative to the catheter shaft is used to deliver the stent. Regarding claims 28, 30 and 32, the stabiliser component is fixed to a procedural catheter or guide catheter or introducer sheath (column 7, line 66

to column 8, line 6). Regarding claim 39, the stabiliser component position is adjustable (the catheter extends outside of the patient and therefore can be position adjusted when in use; column 7, line 66 to column 8, line 9). Regarding claim 40, the inner core is threaded by the guidewire, as shown in Figure 19, and can be rotated to adjust the position of the stabiliser via member 62 (Figure 6). Regarding claims 41 and 43-47, an intermediate component is provided between the stabiliser component and the inner core comprising at least one bridging piece wherein the bridging piece extends through the wall of the proximal shaft, wherein the bridging piece projects laterally of, or radially between, the inner core and the stabiliser component; wherein the stabiliser component and the inner core are directly mounted to one another (a pin 62 projects radially/laterally between and connects the stabiliser to the inner core; Figure 6; column 7, line 66 to column 8, line 13). Regarding claim 50, the stabiliser component and the inner core are directly mounted to one another proximal of the distal sheath (as can be seen in Figure 6, the inner core 34 and stabiliser 60 can be mounted to one another proximally of the distal end of the catheter where the catheter shaft can comprise a short section of tubing at the distal end of the catheter connected by a pull-wire; Figure 22B). Regarding claims 52-53 and 57-59, the system includes a guidewire and the guidewire extends at least the length of the catheter shaft; the inner core defines a guidewire lumen along the length thereof; the guidewire is located within the profile of the stabiliser component; the stabiliser component has a proximal opening to allow backflow of blood; the stabiliser component extends substantially the length of the catheter shaft (as can be seen in Figure 19, the catheter can contain a guidewire which

extends within and through the inner core, 252 or 35, and past the catheter shaft or sheath; the sheath 76 can be contained within the stabilizer which can extend a significant length thereof; Figure 7). Regarding claims 60, 61, 63 and 67, all limitations not addressed here have been addressed in regard to claim 1. As can be seen in Figure 6, the journal sleeve 60 is the external sheath (and can be gripped as a handle) and mounted to the inner core 34 through an internal connection; the catheter shaft 32 (misabeled 34, see column 8, lines 2 to 3) has a handle 40 (which must be connected to the shaft by a connector) which can be used to slide (or pull) the catheter shaft proximally of the journal sleeve (or stabiliser, or external mounting) and inner core to deploy the stent (Figures 3-5; column 7, lines 49 to 52). Regarding claims 64-66, the connector extends through the external mounting; the connector comprises an elongate member; the elongate member comprises a pull wire (the catheter shaft can comprise a short section of tubing at the distal end of the catheter connected by a pull-wire; Figure 22B; column 12 – lines 6 to 17), the pull wire is shown to extend parallel to the inner shaft and inherently would be drawn through the journal sleeve (or external mounting). Regarding claim 68, a guidewire exit port is provided at the proximal end of the external mounting (Figure 19 shows that the inner core 256 can contain a guidewire and since the inner core exits through the stabiliser 60 as in Figure 6, so must the guidewire.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the



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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 9-11 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Leschinsky (US 6,306,145).

Regarding claims 9-11 and 18-19 Lenker et al. disclose that the stabiliser component is disposed over the smaller diameter proximal shaft (it can be clearly seen that the stabilizer 60 is disposed over the catheter shaft 32; Figure 6). Lenker et al. fail to disclose that the catheter shaft comprises a distal sheath portion and a proximal shaft portion, the diameter of the proximal shaft portion being smaller than the diameter of the distal sheath portion; wherein the stabiliser comprises a tube and the diameter of the stabiliser tube is not greater than the diameter of the distal sheath of the catheter shaft; wherein the system comprises a guidewire and the sum of the diameter of the guidewire and the diameter of the proximal shaft is less than the diameter of the distal sheath; wherein the sum of the diameter of the guidewire and the diameter of the stabiliser component is less than the diameter of the distal sheath. Leschinsky teaches that it is advantageous to construct a catheter with a distal sheath portion which is of greater diameter than the proximal shaft portion and of equal or greater diameter to the

introducer sheath (or stabiliser) so that the introducer sheath can be inserted without increasing diameter of the skin puncture, which would minimize trauma to the patient, and so that smaller sized catheters can be used in order to minimize blood flow restriction (Abstract, column 2 - lines 21 to 34, column 5 – lines 65 to 67). It would be obvious to one of ordinary skill in the art to combine the invention of Lenker et al. with a reduced diameter proximal shaft and stabiliser taught by Leschinsky, in order to minimize trauma to the patient and minimize blood flow restriction, where the stabilizer is of less diameter than the distal sheath in order to easily fit through the puncture site used by the distal sheath. To further teach the limitations of the claims (which are already met by the above description), the invention of Lenker could be used in a rapid exchange configuration, which would be an obvious design choice to one of ordinary skill in the art, where the guidewire is external to the catheter shaft except at the distal end. In this arrangement, the sum of the guide wire diameter and stabilizer diameter would have to be less than the diameter of the distal sheath.

11. Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Leschinsky (US 6,306,145), as applied to claim 9 above, and in further view of Healy et al. (EP 1095634).

Regarding claims 12-17, Lenker et al. in view of Leschinsky disclose the delivery system as described above. Lenker et al. in view of Leschinsky does not teach that the catheter shaft has a guidewire exit port which is located proximally of the distal end of the catheter shaft; wherein the guidewire exit port is located proximally of the stent and delivery sheath; wherein the guidewire exit port is located at a transition between the

distal sheath and the reduced diameter proximal shaft portion; wherein the guidewire exit port is located distally of the stabiliser component; wherein the guidewire exit port is configured to exit along an axis that is substantially parallel to a longitudinal axis of the distal sheath. Healy et al. who disclose a rapid exchange catheter configuration where the guidewire exit port is at an intermediate, transition section 46 (Figure 2) of the catheter shaft, just prior to the delivery sheath 28/30 (Figure 2) and distally of the stabilizer (column 10, lines 52-55) where it exits in a line that is substantially parallel to a longitudinal axis of the distal sheath (Figure 1 at 44). This design addresses the challenge of maintaining alignment of the inner and outer guidewire ports (column 5 – lines 10-11). It would be obvious to one of ordinary skill in the art, to combine the invention of Lenker et al. in view of Leschinsky with the guidewire port configuration of Healy et al. in order to have the operational advantages of a rapid exchange catheter and minimize misalignment of the guidewire exit port during sheath retraction.

12. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Blaeser et al. (US 6,168,617).

Regarding claims 20-22 Lenker et al. disclose a delivery system wherein the inner core comprises a large diameter distal segment and a reduced diameter proximal segment (as described above for claim 3). Lenker et al. do not disclose a transition segment between the distal and proximal segments; wherein the transition segment is proximal of the abutment region; wherein the transition segment is distal of a guidewire exit port. Blaeser et al. disclose a catheter with an inner core 18 (Figure 2) having a reduced diameter transition portion extending through the stent (Figure 2) in order to

reduce the overall diameter of the catheter at the distal end to facilitate ease of movement through arteries and lesion sites (column 2, lines 46 to 59). It would be obvious to one of ordinary skill in the art to have reduced the diameter of the inner core further, in view of Blaeser et al., at least through the stent engaging section which includes abutments (as described for claim 2), in order to reduce the diameter of the distal end of the catheter which would facilitate its movement through arteries and lesion sites.

13. Claims 29, 31, 33-36 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Burns (US 5,032,113).

Regarding claims 29, 31, 33-36, and 54-55 Lenker et al. disclose a system as described above. Lenker et al. do not disclose that a haemostasis gasket is provided between the stabiliser component and the procedural catheter; wherein the introducer sheath has an integral haemostasis gasket; wherein the guide catheter has a haemostasis gasket attachment; wherein the gasket is adjustable by the operator; wherein the gasket attachment is a Touhy Borst; wherein the system comprises a procedural guidewire and the guidewire is fixed or fixable to the stabiliser component; wherein the system includes a lock for the guidewire; wherein the lock is located proximal of the handle. Burns discloses a manifold 21 containing Touhy Borst fittings to provide a hermetic seal for a guidewire 22 and to lock the relative position of the guidewire and catheter tube (Figure 1A; column 4, lines 37-40). Furthermore, Touhy Borst fittings in combination with a manifold can be used to fix the relative position of a catheter tube and guidewire or other catheter tube, whether the catheter tube is a

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stabiliser, introducer sheath or guide catheter. Touhy Borst fittings contain gaskets and form a unitary, or integral, connection with tubes and guidewires. It would be obvious to one of ordinary skill in the art, in view of Burns, to use a Touhy Borst fitting in combination with a manifold to hermetically seal a guidewire to the catheter thereby fixing it, indirectly, to the stabiliser. It would also be an obvious design choice to one of ordinary skill in the art to have connected the stabiliser of Lenker to an introducer sheath or guide catheter via a Touhy Borst fitting, in order to anchor the stabiliser to the introducer sheath or guide catheter as intended by Lenker et al. (column 7, line 66 to column 8, line 6).

14. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view Lenker et al. (US 5,683,451).

Regarding claims 37-38, Lenker et al. disclose the system as described above. Lenker et al. ('685) do not disclose that the stabiliser component is length adjustable; wherein the stabiliser component comprises at least two parts which are movable relative to one another. Lenker et al. ('451) disclose a catheter of very similar design to Lenker et al. ('685) where the stabiliser 38 (Figure 2) contains a slidable piece or slider 50 (Figure 2) which allows for length adjustment of the stabiliser so that it can be fit into an external control device (evident from Figure 33). It would be obvious to one of ordinary skill in the art and to have combined the invention of Lenker et al. ('685) with the slider of Lenker et al. ('451) so that an external control device can be used.

15. Claim 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view Del Toro (US 5,733,267).

Regarding claim 42, Lenker et al. disclose the system as described above.

Lenker et al. do not disclose that the intermediate component comprises the handle.

Del Toro discloses a three-layered catheter of similar design to Lenker et al. where the outer sheath is connected to the inner sheath by an external member 40 at the proximal end of the catheter, where it could be grasped as part of a handle component (Figure 4; column 3, lines 16 to 26). The external member also stabilizes the relative positions of the outer and inner sheaths. It would be obvious to one of ordinary skill in the art to have combined the invention of Lenker et al. with the external member, in view of Del Toro, as an obvious design choice for accomplishing the stated goal of Lenker et al. which is to fix the relative positions of the outer and inner sheaths (stabiliser and inner core, or journey sleeve and shaft).

16. Claims 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Klein et al. (US 5,002,558).

Regarding claims 48 and 49, Lenker et al. disclose system as described above. Lenker et al. do not disclose that the stabiliser component is melded to the inner core by welding, gluing, joining, laminating, or bonding process. Klein et al. who teach that it is known in the art to join an outer sheath to a catheter by using biocompatible glue (column 4; lines 6 to 9). It would be obvious to one of ordinary skill in the art to have joined the stabiliser (which is an outer sheath) to the inner core of the catheter using biocompatible glue.

17. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (US 6,126,685) in view of Harvey et al. (US 4,607,868).

Regarding claim 56, Lenker et al. disclose a system as described above wherein the stabiliser component comprises a tubular element. Lenker et al. do not disclose that the tubular element has a tapered distal end. Harvey et al. teach that it is well known in the medical art to make tube connections by tapering the end of a tube to fit into a leur adapter (column 1; lines 27 to 30). It would be obvious to one of ordinary skill in the art to have connected the stabiliser of Lenker et al. to an introducer sheath (column 4, lines 37 to 39), via a leur adapter and tapered ends as taught by Harvey et al.

### ***Response to Arguments***

18. Applicant's arguments filed April 8<sup>th</sup> 2008 have been fully considered but they are not persuasive. Regarding claim 1 and 60, as stated above, Examiner does not find support in Applicant's specification to consider the term "thumbscrew" as a structure which uses rotational movement to cause linear movement of the catheter shafts. Lenker et al., as described above, show a structure (such as 40) which can be considered as a thumbscrew in the broadest sense. Further regarding claim 60, Applicant argues that Lenker et al. do not disclose the catheter shaft and operator handle being interconnected by a connector. Examiner respectfully disagrees and believes the catheter shaft and handle of Lenker et al. are not so integrated as to not be interconnected by a connector. For example, the knurled knob at 40 of Lenker et al. is connected to the catheter shaft by a structure which can be considered as a connector in a broad sense. Regarding claim 5, Examiner fails to understand how "stiff and incompressible", as cited from Applicant's specification, clarifies the meaning of "compressive stiffness".

***Conclusion***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

20. This action is made FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Mcevoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent

22. Application Information Retrieval (4PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.



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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731